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**PATENT** 

Attorney Docket No. 29914.703.201

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application	<u>PATENT APPLICATION</u>
Inventor(s): David STINSON et al.	)
(-),	) Art Unit: 3732
Application No.: 10/615,417	)
	) Examiner: Kevin P. Shaver
Filed: July 8, 2003	) Confirmation No.: 7968
Title: Prostheses, tools and methods for	) Commination No.: 7908
replacement of natural facet joints with	)
artificial facet joint surfaces	,
	) ·

Commissioner of Patents P.O. Box 1450 Alexandria, VA 22313-1450

## SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97

Sir:

Applicants hereby submit an Information Disclosure Statement along with attached form(s) PTO/SB/08. A copy of each listed publication is being submitted herewith, along with a concise explanation of information in a foreign language, if any, pursuant to 37 C.F.R. §1.97-1.98.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in §1.56.  $\boxtimes$ This statement qualifies under 37 C.F.R.  $\S1.97$ , subsection (b) because: It is being filed within 3 months of the application filing date and is other than (1) a continued prosecution application under § 1.53(d) -- OR --It is being filed within 3 months of entry of a national stage (2) -- OR --冈 It is being filed before the mail date of the first Office Action on the merits (3) -- OR --It is being filed before the mailing of a first Office Action after the filing of a (4) request for continued examination under § 1.114. 37 C.F.R.  $\S1.97(c)$ . If this statement is being filed after the latest of: (1) three months beyond the filing date of a national application; (2) three months beyond the date of entry of the national stage as set forth in §1.491 in an international application; or (3) the mailing date of a first Office action on the merits, but before the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, then: a certification as specified in §1.97(e) is provided below; or a fee of \$180.00 as set forth in \$1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement. 37 C.F.R. §1.97(d). If this statement is being filed after the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, but before payment of the issue fee, then: a certification as specified in §1.97(e) is completed below; and A. a fee of \$180.00 as set forth in \$1.17(p) is authorized below, enclosed, or included B. with the payment of other papers filed together with this statement. Copies of each of the references listed on the attached Form PTO/SB/08 are enclosed herewith. Copies of references listed on the attached Form PTO/SB/08 are enclosed herewith EXCEPT  $\bowtie$ THAT: In view of the voluminous nature of references, and the likelihood that these references are available to the Examiner in the file history of the parent application ), copies are not enclosed herewith. (Serial No. If any of the foregoing publications are not available to the Examiner,

Applicant will endeavor to supply copies at the Examiner's request.

		accordance with 37 CFR 1.98 (	cuments and non-patent literature are enclosed in a)(2). (The U.S. patents and each U.S. patent e attached Form PTO-1449 are not enclosed.)
	There	are no listed references which are no	ot in the English language.
	Japane WO 9 Englis their c Shoul PCT 1	ese Patent Publication 10179622 A205/05783 A1, WO 98/48717 A1 and sh language abstracts and the drawing disclosure.  d the Examiner believe that a compare the compare compar	nich are not in the English language is as follows: 2 was published in Japanese and PCT applications WO 99/23963 A1 were published in French. The ngs of each are sufficient to convey the scope of plete translation of any of the Japanese or French and their disclosure, Applicants will endeavor to request.
		cordance with MPEP 609 D in suj	om corresponding patent application(s), submitted oport of the attached certification under 37 CFR
	Attacl releva	<u> </u>	pending patent applications which may be deemed
	fees o		hereby authorized to charge the above-referenced ees or credit any overpayment associated with this 3-2415 (Docket No.29914.703.201).
			Respectfully submitted,
			WILSON SONSINI GOODRICH & ROSATI
(650)	nge Mil Alto, C <i>A</i> 493-930	A 94304-1050	By: Benjamin Glenn, Reg. No. 44,713
	1101 110		

PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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				Complete if Known		
Substitute for form 1449/PTO				Application Number	10/615,417	
INFORMATION DISCLOSURE				Filing Date	07/08/2003	
	STATEMENT BY APPLICANT			First Named Inventor	Stinson et al.	
(Use as many sheets as necessary)		Art Unit	3732			
<b>W</b>				Examiner Name	Shaver	
Sheet	1	of	4	Attorney Docket Number	29914.703.201	

Examiner	Cite	Document Number	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where
Initials*	No.1	Number-Kind Code <sup>2</sup> (if known)	MM-DD-YYYY	Applicant of Cited Document	Relevant Passages or Relevant Figures Appear
		US-2004/0059429	03/25/2004	Amin et al.	
		US-3,867,728	02/25/1975	Stubstad et al.	
		US-3,875,595	04/08/1975	Froning	
•		US-4,349,921	09/21/1982	Kuntz	
		US-4,759,769	07/26/1988	Hedman et al.	
		US-4,772,287	09/20/1988	Ray et al.	
		US-4,863,477	09/05/1989	Monson	
		US-4,904,260	02/27/1990	Ray et al.	
		US-4,911,718 ·	03/27/1990	Lee et al.	
		US-5,047,055	09/10/1991	Bao et al.	•
		US-5,071,437	12/10/1991	Steffee	
		US-5,147,404	09/15/1992	Downey	
		US-5,171,280	12/15/1992	Baumgartner	
		US-5,192,326	03/09/1993	Bao et al.	
		US-5,306,308	04/26/1994	Gross et al.	
		US-5,306,309	04/26/1994	Wagner et al.	
		US-5,370,697 ·	12/06/1994	Baumgartner	<del>-</del> .
	-	US-5,401,269	03/28/1995	Buttner-Janz et al.	<u>-</u>
		US-5,437,672	08/01/1995	Alleyne	
		US-5,458,642	10/17/1995	Beer et al.	
		US-5,458,643	10/17/1995	Oka et al.	

Examiner		Date	-
Signature	·	Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST .3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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(Use as	s many shee	ts as ne	cessary)	Art Unit	3732	
				Examiner Name	Shaver	
Sheet	2	of	4	Attorney Docket Number	29914.703.201	

Examiner Initials*	Cite No. <sup>1</sup>	Document Number  Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-5,514,180	05/07/1996	Heggeness et al.	riguies Appeai
		US-5,534,028	07/09/1996	Bao et al.	
		US-5,534,030 ·	07/09/1996	Navarro et al.	
		US-5,545,229	08/13/1996	Parsons et al.	
		US-5,556,431	09/17/1996	Buttner-Janz	
		US-5,571,189	11/05/1996	Kuslich	•
		US-5,645,597	07/08/1997	Krapiva	
		US-5,653,762	08/05/1997	Pisharodi	· · · ·
		US-5,674,295	10/07/1997	Ray et al.	
		US-5,674,296	10/07/1997	Bryan et al.	
		US-5,676,701	10/14/1997	Yuan et al.	
		US-5,683,464	11/04/1997	Wagner et al.	
		US-5,702,450	12/30/1997	Bisserie	· · · · · · · · · · · · · · · · · · ·
		US-5,716,415	02/10/1998	Steffee	
		US-5,824,093	10/20/1998	Ray et al.	
		US-5,824,094	10/20/1998	Serhan et al.	
		US-5,865,846	02/02/1999	Bryan et al.	
		US-5,868,745	02/09/1999	Alleyne	
		US-5,893,889	04/13/1999	Harrington	
		US-6,001,130	12/14/1999	Bryan et al.	
		US-6,014,588	01/11/2000	Fitz	- "
		US-6,019,792	02/01/2000	Cauthen	
<del></del>		US-6,039,763	03/21/2000	Shelokov	10
		US-6,063,121	05/16/2000	Xavier et al.	
•		US-6,066,325	05/23/2000	Wallace et al.	
		US-6,080,157	06/27/2000	Cathro et al.	<del></del>
		US-6,113,637	09/05/2000	Gill et al.	
		US-6,132,465	10/17/2000	Ray et al.	
		US-6,669,729	12/30/2003	Chin	

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				Con	nplete if Known
Substitute for	or form 1449	9/PTO	•	Application Number	10/615,417
INFORMATION DISCLOSURE			LOSURE	Filing Date	07/08/2003
	STATEMENT BY APPLICANT			First Named Inventor	Stinson et al.
(Use as	s many sheet	ts as ne	cessary)	Art Unit	3732
				Examiner Name	Shaver
Sheet	3	of	4	Attorney Docket Number	29914.703.201

		FOREIGN	PATENT DO	CUMENTS		
Examiner Initials*	Cite No.1	Foreign Patent Document  Country Code <sup>3</sup> – Number <sup>4</sup> – Kind Code <sup>3</sup> (If known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		DE 10135771 A1	02/20/2003	Aesculap AG & Co.	·	X
-		IE S970323	06/03/1998	Eskina Developments Limited		
		JP 10179622 A2	07/07/1998	Mizuho Ika Kogyo KK		X
		WO 95/05783 A1	03/02/1995	Fairant, Paulette		X
		WO 98/48717 A1	11/05/1998	Taylor, Jean		X
		WO 98/56301 A1	12/17/1998	Kyphon Inc.		1
		WO 99/05995 A1	02/11/1999	Gordon, Maya, Roberts & Thomas Number 1 LLC		-
		WO 99/23963 A1	05/20/1999	Dimso		X
-		WO 99/60957 A1	12/02/1999	Nuvasive, Inc.		
		WO 99/65412 A1	12/23/1999	Pioneer Laboratories, Inc.		
		WO 00/38582 A1	07/06/2000	Nuvasive, Inc.	-	
		WO 00/62684 A1	10/26/2000	Nuvasive, Inc.		1
•		WO 01/30248 A1	05/03/2001	Reiley, Mark A.		
		WO 01/97721 A2	12/27/2001	Kyphon Inc.		
		WO 02/089712 A1	11/14/2002	Gerber, David et al.		
		WO 03/020143 A1	03/13/2003	Synthes		
		WO 03/101350 A1	12/11/2003	Archus Orthopedics Inc.		
		WO 2004/071358 A1	08/26/2004	Archus Orthopedics Inc.	·	
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INFORMATION DISCLOSURE				Filing Date	07/08/2003
STATEMENT BY APPLICANT				First Named Inventor	Stinson et al.
(Use d	(Use as many sheets as necessary)		Art Unit	3732	
				Examiner Name	Shaver
Sheet	4	of	4	Attorney Docket Number	29914.703.201

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		GOH, JC et al., "Influence of PLIF cage size on lumbar spine stability", Spine, (January 2000), 25(1) Medline abstract (one page).	
		HEAD, WC, "Wagner surface replacement arthroplasty of the hip. Analysis of fourteen failures in forty-one hips", <i>J Bone Joint Surg. Am.</i> , (March 1981) 63(3), Medline abstract (one page).	
		KHOO, LT et al., "A biomechanical analysis of the effects of lumbar fusion on the adjacent vertebral motion segment", Proceedings of the 2000 Annual Meeting of the North American Spine Society, New Orleans.	
		KOTANI, Y. et al., "The effects of spinal fixation and destabilization on the biomechanical and histologic properties of spinal ligaments. An in vivo study.", <i>Spine</i> , (March 15, 1998) 23(6), Medline abstract (2 pages).	
		LEMAIRE, JP et al., "Intervertebral disc prosthesis: results and prospects for the year 2000", Clinical Orthopaedics and Related Research, No. 337, pp. 64-76.	
		NAGATA, H. et al., "The effects of immobilization of long segments of the spine on the adjacent and distal facet force and lumbrosacral motion", <i>Spine</i> , (December 1993), 18(16):2471-2479, (9 pages).	
		NIBU, K. et al., "Multidirectional stabilizing potential of BAK interbody spinal fusion system for anterior surgery [see comments]", <i>J Spinal Discord</i> , (August 1997), 10(4), Medline abstract (one page).	
		TSANTRIZOS, A. et al., "Segmental stability and compressive strength of posterior lumbar interbody fusion implants", <i>Spine</i> , (August 1, 2000) 25(15), Medline abstract (one page).	
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Examiner	. Dat	e
signature	Cor	nsidered

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